



MAY 19 2004

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May 19, 2004

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Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Art Unit 1644

Mail Stop AF

Re: U.S. Utility Patent Application
Application No. 09/920,332; Filed: August 2, 2001
For: Method of Identifying Immunosuppressive Agents
Inventors: Kasibhatla *et al.*
Our Ref: 1735.0470001/RWE/ALS

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Reply Under 37 C.F.R. § 1.116; and
2. Return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Robert W. Esmond
Attorney for Applicants
Registration No. 32,893

RWE/dab
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Enclosure



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AF/1644

Reply Under 37 C.F.R. § 1.116
Expedited Procedure - Art Unit 1644

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| | |
|--------------------------------------------------------|------------------------------------|
| In re application of: | Confirmation No.: 5774 |
| Kasibhatla <i>et al.</i> | Art Unit: 1644 |
| Appl. No.: 09/920,332 | Examiner: Huynh, Phuong N. |
| Filed: August 2, 2001 | Atty. Docket: 1735.0470001/RWE/ALS |
| For: Method of Identifying Immunosuppressive Agents | |

Reply Under 37 C.F.R. § 1.116

Mail Stop AF

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

In reply to the Office Action dated February 26, 2004 (hereinafter "Office Action"), Applicants submit the following Remarks. Claims 1, 2, 4-7, 9-13, 28-31 and 36-44 are pending in the application, with claims 1, 28 and 31 being the independent claims. Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

Rejections under 35 U.S.C. § 103

Claims 1-2, 4-7, 9-11, 28-31 and 36-42 are rejected under 35 U.S.C. §103(a) as being unpatentable over Evans, D. L. *et al.*, *Cancer Research*, 54: 1596-1603 (1994) ("Evans *et al.*") in view of Porter, D. H. *et al.*, *Analytical Biochemistry*, 123: 41-48 (1982) ("Porter *et al.*") and U.S. Patent No. 6,342,611 ("the '611 patent"). Office Action, pages 2-8. Claims 12-13, 43 and 44 are also rejected under 35 U.S.C. §103(a) as being

unpatentable over Evans *et al.* in view of Porter *et al.* and the '611 patent as applied to claims 1-2, 4-7, 9-11, 28-31 and 36-42 and further in view of Wesselborg, S. *et al.*, *Eur. J. Immunol.*, 23: 2707-2710 (1993) ("Wesselborg *et al.*"). Office Action, pages 9-13. Applicants respectfully traverse the rejection.

Applicants respectfully assert that the '611 patent cannot properly be used in a rejection under 35 U.S.C. § 103(a) because of the provision found in 35 U.S.C. § 103(c). This section provides as follows:

Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

35 U.S.C. § 103(c). Moreover, the MPEP explicitly states that this section "applies to all utility, design and plant patent applications filed on or after November 29, 1999," MPEP (Eighth, rev. 1) § 706.02(k), page 700-45 (February 2003). Applicants' application was filed on August 2, 2001, and the above section is applicable.

The subject matter of the captioned application was developed by Shailaja Kasibhatla, Douglas R. Green and Ben Tseng. *See* original executed declaration filed on November 15, 2001. In contrast, the subject matter of the '611 patent was developed by Eckard Weber, Sui Xiong Cai, John F.W. Keana, John A. Drewe and Han-Zhong Zhang. *See* first page of the '611 patent. Hence, the subject matter of the '611 patent was developed by another person.

The '611 patent qualifies as prior art (if it qualifies as prior art at all) only under one or more of subsections (e), (f), and (g) of 35 U.S.C. § 102. 35 U.S.C. § 102(a) and (b) are not applicable because the '611 patent published on January 29, 2002, which is

after the filing date of the instant application (August 2, 2001) and after the priority date of the instant application (August 3, 2000). Furthermore, 35 U.S.C. § 102(c) and (d) are not relevant or applicable to the '611 patent. Hence, the '611 patent qualifies as prior art (if it qualifies as prior art at all) only under one or more of subsections (e), (f), and (g) of 35 U.S.C. § 102.

Finally, the subject matter of the '611 patent and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. The MPEP sets forth the requisite evidence required to establish common ownership:

The following statement is sufficient evidence to establish common ownership of, or an obligation for assignment to, the same person(s) or organizations(s):

Applications and references (whether patents, patent applications, patent application publications, etc.) will be considered by the examiner to be owned by, or subject to an obligation of assignment to the same person, at the time the invention was made, if the applicant(s) or an attorney or agent of record makes a statement to the effect that the application and the reference were, at the time the invention was made, owned by, or subject to an obligation of assignment to, the same person.

MPEP (Eighth, rev. 1) § 706.02(l)(2)(II), p. 700-53 (February 2003) (*referring to* "Guidelines Setting Forth a Modified Policy Concerning the Evidence of Common Ownership, or an Obligation of Assignment to the Same Person, as Required by 35 U.S.C. 103(c)," 1241 O.G. 96 (December 26, 2000)). The undersigned hereby asserts that the ownership of the present application and the '611 patent were, at the time the present invention was made, owned by, or subject to an obligation of assignment to the same person. Hence, Applicants have provided sufficient evidence establishing that the subject matter of the '611 patent and the claimed invention were, at the time the

invention was made, owned by the same person or subject to an obligation of assignment to the same person. Accordingly, Applicants have demonstrated that because the '611 patent falls within the ambit of 35 U.S.C. § 103(c), it cannot properly be used in a rejection under 35 U.S.C. §103(a).

Furthermore, the Examiner bears the initial burden of establishing a *prima facie* case of obviousness under 35 U.S.C. § 103. In particular, the MPEP sets forth the criteria necessary to satisfy this burden:

To establish a *prima facie* case of obviousness, three basic criteria *must* be met. First, there *must* be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there *must* be a reasonable expectation of success. Finally, the prior art reference (or references when combined) *must* teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success *must* both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See MPEP § 2143 - § 2143.03 for decisions pertinent to each of these criteria.

MPEP (Eighth, rev. 1) § 2142, page 2100-124 (February 2003), emphasis added. Applicants respectfully assert that the references cited in support of the 35 U.S.C. § 103 rejection do not meet these criteria, and that consequently the Examiner has not established a *prima facie* case of obviousness.

Hence, the new grounds of rejection under §103 have been overcome and Applicants respectfully ask the Examiner to reconsider and withdraw the rejection under 35 U.S.C. §103(a).

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Reply is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Robert W. Esmond
Attorney for Applicants
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Date: May 19, 2004

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